

REMARKS/ARGUMENTS

Claims 1-16 are currently pending in the above-identified application. Claims 1, 6 and 15 have been amended. The phrase found in claim 6 that the "antibody does not react with the at least one immuno-cross reactive antigen component" has been incorporated into claim 1. Claims 1 and 15 have also been amended to specify that the antibody which is added is one that reacts with the mycobacterial species for which detection is sought. No new matter has been added.

Claim Rejections under 35 U.S.C. § 112

Claims 1-16 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Office states that the previous response was persuasive concerning the detection of whole *Mycobacterium*, however it remained unclear how a species is identified if one adds both ≥ 1 ImCRAC and ≥ 1 antibody which already binds to the ImCRAC. Claim 1 has been amended to specify that the antibody does not bind to the ImCRAC, this language being taken from dependent claim 6, and is consistent with the language used elsewhere, e.g., independent claim 15. Thus, the basis for the rejection under 35 U.S.C. §112, second paragraph, has been obviated and its withdrawal is respectfully requested.

The rejection of claims 1-16 under 35 U.S.C. 112, first paragraph, based on scope has been maintained. The Office alleges the specification only teaches that *M. tuberculosis* is identified, and sufficient guidance is not provided for identifying a species of *Mycobacterium* by using ≥ 1 ImCRAC from different species and ≥ 1 antibody capable of reacting with another mycobacterial antigen.

Applicants have amended claims 1 and 15 to more distinctly point out that the mycobacterial antigen which reacts with the antibody is from the species which the ImCRAC component is from. Thus, the Examiner's concern that using an ImCRAC from a species

different from the mycobacterial antigen recognized by the antibody has been obviated. The present specification teaches that ImCRACs can form banding patterns, or "bar-codes," that are characteristic of particular mycobacterial species. The ImCRACs can be used to identify a particular species an individual is infected with. Although the specification contains particular experimental examples detailing the use of the banding patterns in the present invention for diagnosing the presence of infections due to *M. tuberculosis*, the same approach with the ImCRACs is to be used with the other species of Mycobacteria. See, e.g., the discussion of ImCRACs at page 6, line 28, to page 7, line 19, and elsewhere. At page 7, line 20, the specification discusses preferred ImCRAC fractions for Mycobacteria. Thus, consistent with the teachings of the specification, the ImCRACs can be used to detect the presence of Mycobacteria not limited to *M. tuberculosis*. In the absence of teachings or specific reasoning or evidence to the contrary, the presently claimed invention must be considered to be fully enabled in a manner that complies with 35 U.S.C. §112, first paragraph. Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

Double Patenting

Claims 1-16 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of the issued parent case, U.S. Patent No. 6,733,983. Although Applicants respectfully disagree with the position of the Office regarding the patentable distinctness of the present claims, Applicants submit herewith from the owner of the present application and U.S. 6,733,983 a terminal disclaimer that disclaims the terminal part of the statutory term of any patent granted on the present application, which would extend beyond the expiration date of the full statutory term of prior U.S. Patent No. 6,733,983.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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